FY2010 Appropriations Request Form

Office of Congresswoman Jackie Speier
211 Cannon House Office Building
Washington, D.C. 20515
Phone: 202/225-3531
Fax: 202/226-4183
Website: www.speier.house.gov

Individuals/Organizations must respond to all questions on the form. Incomplete proposals will not be considered. All requests will be evaluated before the 12th Congressional District's Citizens Oversight Panel. Appointments to appear before the panel must be made through Cookab Hashemi, chief of staff, at 202/225-3531 or Cookab.Hashemi@mail.house.gov. The panel will convene on the following days; Saturday, March 7, Friday, March 13 and Friday, March 20, 2009. All proposals must be submitted by March 2, 2009.

Date Submitted: March 2, 2009

Project Name: Design of clinical trial for influenza treatment

Individual/Organization: Gemmus Pharma Inc. 1345 Hillcrest Blvd Millbrae, CA 94030. The organization is located within the California 12th Congressional District.

Amount Requested: $200,000.00

Appropriations Bill/Account/Relevant Authorization law/bill/status: FY 2010 Omnibus Appropriations Act and related

Local Contact:
Daryl Faulds Ph.D.
Chief Executive Officer
Gemmus Pharma Inc.
1345 Hillcrest Blvd
Millbrae, CA 94030
Cell: (415) 497 0792
Phone: (650) 259 7814

Organization's Main Activities. Gemmus Pharma Inc., a private for-profit project development organization, was incorporated in August, 2007 for the purpose of conducting research and development on new therapeutics for infectious disease. While employed by a large German pharmaceutical company the founders of Gemmus Pharma invented a new method for the treatment of influenza. In March, 2007, the United State corporate research and development employees, both in Connecticut and California, were laid off and corporate R&D was relocated to Germany. As employees in good standing prior to the layoffs, the founders obtained an exclusive world-wide development license for two projects and established Gemmus Pharma.

The Gemmus Pharma approach is to identify compounds which have successfully completed at least Phase I clinical testing (human safety) and retarget them for the treatment of seasonal Influenza A hospitalizations, pandemic influenza, and other serious diseases caused viral infections. Unlike

traditional antiviral therapies, Gemmus has taken an alternative approach to the treatment of viral infection by focusing on our body's response to the virus rather than on the virus itself. Our first candidate therapeutic for influenza is GP1001, an eicosanoid for oral administration, which is efficacious in animal models, has a clinically established safety profile and can be manufactured.

Please show main items in the project and total cost in a simplified chart form.

The following activities would be carried out by Pacific BioDevelopment of San Bruno, CA at an initial cost of $100,000, abbreviations defined below:

I. Clinical Trial:

- Develop Detailed Description for the Clinical Evaluation of GP1001 $50,000
- Conduct Pre-IND discussion with Kenny Shade, Regulatory Health Project Manager, FDA/CDER/OND/OAP/Division of Antiviral Products
- Document conformity with IND application process $50,000
- Redesign trial (if necessary) Gemmus

II. Regulatory Activities needed for clinical trials $100,000

- Complete Pre-IND evaluation
- Prepare preliminary manufacturing design
- Review legal and patent considerations
- Conduct product safety review
- Perform evaluate/predict product cycle time
- Update financial analysis
- Risk analysis
- Review preliminary investigation criteria
- Develop pilot stage plan

Project Description, including a timeline, goals, expected outcomes and specific uses of Federal Funds.

The requested Federal Funds would be used over the next 6 to 12 months to prepare clinical and regulatory plans for submission to the Federal Drug Administration (FDA) of an Investigational New Drug (IND) application for our lead compound GP1001 as a treatment for influenza infections. The work would be carried out with Pacific BioDevelopment of San Bruno, CA who has extensive experience and success in submitting applications to the FDA. The application will be based on the results obtained from the National Institute of Allergy and Infectious Disease (NIAID)-funded animal studies carried out at a National Institutes of Health (NIH) contract laboratory. The ultimate goal of the project is to have a treatment for pandemic influenza infections available to public health agencies in California which could be used in combination with existing stockpiled anti-viral therapies.

How will this earmark serve to expand the capacity of your organization and how will your organization sustain this work beyond the federal funding?

Although influenza is a very old disease the Gemmus Pharma approach represents a new direction in therapy. Our immunomodulatory approach represents a departure from vaccines and traditional antiviral therapy. A new drug for a serious disease requires FDA licensure and compliance with standard goals of safety and efficacy. For a new therapeutic approach, this represents a serious challenge.

Our results to date are promising. We have shifted the body's response to disease, rather than attacking the virus directly. The human safety profile is acceptable. The goal of this federal funding is to assist Gemmus Pharma in working with the FDA to help advance this novel approach. We believe GP1001

represents the first of many immunomodulators for infectious disease that will obtain FDA approval. The federal funding we request will help establish useful precedents for other immunomodulators that will follow.

Receipt of Federal Funds would allow us to hire additional personal and would allow us to obtain matching funds from either Angel Investors or Venture Capital Firms. Federal funding would provide access to other government public health agencies at the local, state, and federal levels.

What is the local significance of this project? Jobs and improved health care are the goals of this project. The pharmaceutical industry, both locally and nationally, has experienced a significant reduction in size, in both the number of employees and companies. The result has been a large number of highly trained and experienced professionals who are available and interested in working in small pharmaceutical or biotechnology companies. At the same time, the pharmaceutical industry has shifted its business model toward the purchase of promising research programs from smaller companies. A case in point is Gemmus Pharma Inc. which was formed by two downsized pharmaceutical scientists to complete the development of a promising treatment for influenza infections. In the event of an pandemic influenza outbreak, the reduction in morbidity and mortality locally or worldwide would minimize the impact on society.

How many residents of the 12th CD will benefit from this project?
Immediate benefit: The requested funds would help support three positions at Gemmus Pharma Inc of Millbrae, CA and ten positions at Pacific BioDevelopment of San Bruno, CA.

Expected benefit: Every year in the United States, on average 5% to 20% of the population gets the flu; more than 200,000 people are hospitalized from flu complications; and about 36,000 people die from flu. Some people, such as older people, young children, and people with certain health conditions (such as asthma, diabetes, or heart disease), are at high risk for serious flu complications. We believe our results indicate GP1001 may have significant therapeutic value in humans. GP1001 may serve as stand-alone therapy for lethal influenza infection or as adjunct immunomodulatory therapy in combination with current anti-viral therapy reducing hospitalizations and deaths.

Pandemic benefit: A pandemic is a global disease outbreak. A flu pandemic occurs when a new influenza virus emerges for which people have little or no immunity, and for which there is no vaccine. The disease spreads easily person-to-person, causes serious illness, and can sweep across the country and around the world in very short time. It is difficult to predict when the next influenza pandemic will occur or how severe it will be. Wherever and whenever a pandemic starts, everyone around the world is at risk. The consequences for world travel, commerce and health are negative. We believe our results indicate GP1001could be used for treatment of first responders and health care workers, diminishing the spread of the disease.

List any other organizations or state/local elected officials who have expressed support for the project in writing. The National Institute of Allergy and Infectious Disease (NIAID) of the National Institutes of Health (NIH) has provided support for Gemmus Pharma Inc. in the form of testing leading candidate in animal model of avian flu.

Does the organization have any other funding requests for this project?
Federal:
Department of Health and Human Services (DHHS) in response to solicitation, RFP-BARDA-08-28. The solicitation is to support the development of treatments which can target innate immunity and act synergistically with existing, stock-piled anti-viral drugs.
NIH Small Business Innovative Research PA 08-050 (Two applications).

Private:
Bill and Melinda Gates Foundation, Grand Challenge 2 program.
Harvard University Business School, Harvard Angels.

Has the organization previously received Federal funds for this project? Although we have not received direct funding from the National Institute of Allergy and Infectious Diseases (NIAID), program managers have supported the testing of our lead drug candidate at a NIH contract laboratory.

Please attach a list of your organization's staff and board members.
Executive Staff:
Daryl Faulds Ph.D. CEO and Co-Founder
William J. Guilford Ph.D. President and Co-founder
Advisory Board:
Dale L. Barnard Ph.D.
John Parkinson Ph.D.
Tina Singh, Singh Law Corporation

Please attach any additional relevant materials.

Support letter from Heather Greenstone Ph.D. Program Officer, Virology Branch, Division of Microbiology and Infectious Diseases, NIAID, NIH .
Support letters from SBIR grant application.
Dr. Barnard's principle research at Utah State University has been in antiviral chemotherapy and toxicology, both in antiviral screening and in secondary in vivo antiviral studies supported by National Institutes of Health, the U.S. Army Medical Institute, and various pharmaceutical companies. Current research focuses on developing treatments for SARS-CoV, influenza H5N1, and viruses of biodefense importance.
Cover page of patent publication WO 2008/058766 A1 (Designated states in this document designate those countries where the patent has applicability.)
Cover page of exclusive, perpetual, irrevocable license agreement in all countries covered by patent.

From: "Heather Greenstone (NIH/NIAID) [E]" <HGREENSTONE@niaid.nih.gov>
To: wguilford@comcast.net
Sent: Thursday, January 10, 2008 9:35:24 AM GMT -08:00 US/Canada Pacific

Hi Bill,
We have decided to undertake testing of your material in the mouse-influenza model. The plan would be to perform the testing with a view toward combination therapy with a known antiviral. We believe this would be our best shot for achieving a positive result. I believe we discussed this idea over the phone. Please let me know your thoughts on this approach.
Thanks for the reminder call yesterday. Sometimes I need that.
Best Regards,
Heather

Heather L. Greenstone, PhD
Program Officer
Virology Branch
Division of Microbiology and
Infectious Diseases, NIAID, NIH
Room 4089
6610 Rockledge Drive, MSC 6603
Bethesda, MD 20892-6603
(Zip for Express Mail is 20817)
Phone: 301-496-7453
FAX: 301-480-1594
e-mail: hgreenstone@niaid.nih.gov

August 1, 2008

Dear Drs. Faulds and Guilford:

This is to inform you that I would be very happy to collaborate with you on your project in developing selected G protein-coupled protein receptor agonists as possible treatments for virus infections. As you know we are excited about the results from the influenza A H5N1 studies from our existing collaboration and look forward to assisting you with this current endeavor.

I understand that my role in this collaboration is to supervise the proposed CPE/NR and virus yield reduction antiviral assays and analyze the data generated from those assays.

Sincerely yours,

Dale L Barnard

Dale L. Barnard, PhD

Mariko Nagashima, Ph.D.
Biopharmaceutical Consultant
2409 Palmer Avenue
Belmont, CA 94002

July 25th, 2007

Small Business Concern

To Whom It May Concern:

I am writing this letter in support for the grant application entitled "G Protein-Coupled Receptor agonist as Highly Pathogenic Avian Influenza A Therapeutic" submitted by Dr. Daryl Faulds as Principal Investigator of Trinh-Faulds Health LLC. The proposed project evaluates the therapeutic potential of a synthetic prostacyclin derivative for effective treatment of highly pathogenic avian influenza virus A. In the past decade, one such G protein-coupled receptor (GPCR) agonist has been developed and tested mainly by Japanese pharmaceutical companies. The new application for the marketed GPCR agonist for the treatment of highly deadly strain of avian influenza addresses an important problem, how can we better prepare for an influenza pandemic. If proven pre-clinically and clinically, this new influenza therapeutic would have significant commercial potential after a relatively fast-track development and approval process, potentially saving thousands of lives.

My contribution to this proposal relates to the Commercialization Plan, specifically, partnering with larger companies. I intend to initiate contact and facilitate negotiation of licensing deals with relevant Japanese pharmaceutical companies pertaining to the new application and production of the GPCR agonist. With in-depth scientific knowledge, and familiarity with Japanese language and culture, combined with some experience in dealing with Japanese companies, I would provide my service as a consultant on the clinical business aspect of this project on behalf of Trinh-Faulds Health LLC. For my service, Trinh-Faulds Health LLC will be billed at an hourly rate of US$100 and reimbursement of any traveling expense to Japan. An estimated remuneration for the project is US$2,000 plus airfare (economy class) and expense in Japan.

My research career in the pharmaceutical industry spans over 15 years, starting as a post-doctoral fellow at Genentech Inc (South San Francisco, CA) after completion of a B.Sc. with Honors and a Ph.D. degree in Biochemistry from University of Melbourne, Australia. I gained my expertise and management skills in discovery and evaluation of new therapeutic targets in the areas of cardiovascular diseases, immunology and regenerative medicine at Berlex Biosciences (Richmond, CA), the US subsidiary of Schering AG (now Bayer Schering Pharma AG). In 2004, I launched an independent consulting career, conducting scientific and market analyses and assisting business opportunities for Japanese biotechnology companies. I am also involved in Japan Bio Community (www.j-bio.org), a nonprofit organization that promotes advancement of science and business amongst Japanese researchers, students and business people both in the Bay area and in Japan.

I look forwards to contributing to the success of this project spearheaded by Dr. Faulds.

Sincerely

Mariko Nagashima, Ph.D.
Biopharmaceutical Consultant

CONFIDENTIAL

LICENSE AGREEMENT

THIS LICENSE AGREEMENT (this "Agreement") is made and entered into effective as of October 1, 2008 ("Effective Date"), by and between Bayer Schering Pharma AG ("Licensor") and Gemmus Pharma Inc., a Delaware corporation ("Licensee").

WHEREAS, the founders of Licensee were employees in good standing with Schering AG prior to the merger of Schering AG and another company, forming Licensor and such founders were identified as inventors of the Invention (as defined herein) in the patent filing related to the same in their role as such employees; and+

WHEREAS, Licensee desires to obtain certain licensing rights in the Invention and Licensor desires to grant the same to Licensee as cooperative, interested parties dedicated to advancing the use of the Invention.

NOW THEREFORE, in consideration of the covenants and agreements set forth herein and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, Licensor and Licensee hereby agree as follows:

1. DEFINITIONS

1.1 "Invention" means the use of compounds, alone or in combination with each other, and/or with any other compound, excipient, ingredient, stabilizer, or the like, as a therapeutic for the treatment of human respiratory diseases associated with influenza A viruses, such as for example H5N1 and its mutations.

1.2 "Patent Rights" means International patent application WO 2008058766, the corresponding US patent application, and corresponding foreign patents and patent applications and any reissues, extensions, substitutions, continuations, divisions, and continuation-in-part applications (but only those claims in the continuation-in-part applications that are entirely supported in the specification and entitled to the priority date of the parent application), and any patents issuing therefrom.

1.3 "Licensed Field" means manufacture, use, or sale of Licensed Products for treatment of human respiratory diseases associated with influenza A viruses.

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
22 May 2008 (22.05.2008)

PCT

(10) International Publication Number
WO 2008/058766 A1

(51) International Patent Classification:
A61K 31/5575 (2006.01) *A61K 31/5585* (2006.01)
A61K 31/5578 (2006.01) *A61P 31/16* (2006.01)

(21) International Application Number:
PCT/EP2007/009996

(22) International Filing Date:
14 November 2007 (14.11.2007)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
60/859,590 16 November 2006 (16.11.2006) US

(71) Applicant *(for all designated States except US)*: **BAYER SCHERING PHARMA AKTIENGESELLSCHAFT** [DE/DE]; Müllerstrasse 178, 13353 Berlin (DE).

(72) Inventors; and

(75) Inventors/Applicants *(for US only)*: **FAULDS, Daryl** [US/US]; 136 Reed Blvd, Mill Valley, California 94941 (US). **GUILFORD, William, J.** [US/US]; 1881 Robin Whipple Way, Belmont, CA 94002 (US). **SEIFERT, Wolfgang** [DE/DE]; Argentinische Allee 15a, 14163 Berlin (DE).

(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BH, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RS, RU, SC, SD, SE, SG, SK, SL, SM, SV, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IS, IT, LT, LU, LV, MC, MT, NL, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Declaration under Rule 4.17:
— *of inventorship (Rule 4.17(iv))*

Published:
— *with international search report*
— *before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments*

(54) **Title:** EP2 AND EP4 AGONISTS AS AGENTS FOR THE TREATMENT OF INFLUENZA A VIRAL INFECTION

(57) **Abstract:** The present invention is directed to the use of EP2 and/or EP4 agonists as therapeutics for the treatment of diseases associated with influenza A viruses, such as for example H5N1 and mutations thereof.

WO 2008/058766 A1